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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,281	10/13/2000	Hyun Kim	GI 5387	9127

7590 03/05/2003
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EXAMINER

WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/05/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/687,281

Applicant(s)

KIM ET AL.

Examiner

Jon P Weber, Ph.D.

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1651

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 December 2002 (amendment originally filed on 10 September 2002) has been entered. Claims 1-7 and 11 remain to be considered on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1-5, 7 and 11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al. (US 5,939,974).

It is argued that Valentini disclose implantable compositions, not injectable ones as required by the amended claims. It is urged that the solution referenced in the Office action is only a blending of solutions prior to formation of the scaffold, which is then implanted.

The instant claims are drawn to a composition having functional intended use. It is noted that the scaffolding is formed from the mixed solution by drying from the wet state, preferably by lyophilization without freezing (column 7, lines 22-24). Hence, it is clear that prior to drying, Valentini disclose a solution that meets the limitations of the instant claims. The same preferred

Art Unit: 1651

hyaluronic acid esters - HYAFF[®], the same pore-forming agents, the same tricalcium phosphate and several of the same BMPs, and the same solubilizing organic solvents are explicitly recited as being parts of this composition. There is no indication that the solutions are not injectable, just that it is preferred to dry the solutions to form an implantable porous scaffold.

Applicant's arguments filed 10 September 2002 have been fully considered but they are not persuasive. The rejection is adhered to for the reasons of record and the additional reasons above.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al. (US 5,939,974) in view of Wozney et al. (6,187,742).

The teachings of Valentini et al. (US 5,939,974) have been discussed above. Valentini et al. (US 5,939,974) lack BMP-7 (instantly called OP-1.

The teachings of Wozney et al. (6,187,742) have been discussed at page 5 of the Office action of 17 May 2001.

A person of ordinary skill in the art at the time the invention was made would have been motivated to substitute the BMP-7 as taught by Wozney et al. (6,187,742) for the BMPs in the composition as taught by Valentini et al. (US 5,939,974) because Wozney et al. (6,187,742) disclose that their BMPs can be formulated in to carriers including porous particulate polymers, hyaluronic acid and TCP.

The art of record shows that BMPs have been formulated with a range of suitable carriers. The only requirement for formulation appears to be compatibility with the bone matrix to which it is being added. Hence, given that the carriers of Wozney et al. (6,187,742) are

Art Unit: 1651

functionally equivalent and nearly the same as those of Valentini et al. (US 5,939,974) (hyaluronic acid as compared to hyaluronic acid esters) it would involve nothing more than an arbitrary matter of experimental design choice to select one carrier over another. Such a choice is within the skill of the ordinary artisan of bone repairs.

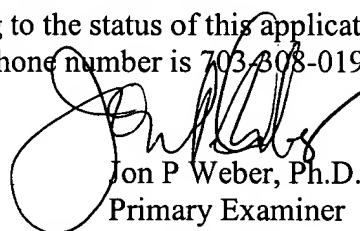
Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the BMP-7 of Wozney et al. (6,187,742) for the BMPs in the composition as taught by Valentini et al. (US 5,939,974).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
February 28, 2003